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No. 343

IN THE

Supreme Court of the United States

OCTOBER TERM, 1968

UNITED STATES,

Petitioner,

v.

AN ARTICLE OF DRUG * * * BACTO-UNIDISK * * *

Petition of Respondent Difco Laboratories, Inc. for Rehearing of Decision Reversing Judgment of the United States Court of Appeals for the Sixth Circuit

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Respondent Difco Laboratories, Inc. petitions this Court for rehearing of its decision of April 28, 1969, reversing the judgment of the United States Court of Appeals for the Sixth Circuit that the article Bacto-Unidisk is not a "drug" and, upon such rehearing, for affirmance of the judgment of the Court of Appeals.

REASONS FOR GRANTING REHEARING AND AFFIRMING THE JUDGMENT OF THE COURT OF APPEALS

It is apparent that there are a number of basic and critical aspects of the facts and the law of this case which have been overlooked and others which have been misunderstood, by the Court. This is clear from the lengthy

questioning by justices during the oral argument and more significantly, from the opinion of the Court itself. The important oversights and misunderstandings which constitute the reason for our request for a further hearing, are set forth hereinafter.

I. The sensitivity test, of which the disk is an element, is not used in diagnosis. There can be no reasonable question on this point. "Diagnosis" is recognition of a disease or illness. A disease cannot be recognized on the basis of the information derived from the sensitivity test since the test does *not* identify the organism which caused the disease. Since the evidence showed and the District Court found that identification of the organism is a step *preliminary* to the sensitivity testing procedure (App. 118, 119; Finding of Fact Number 7, App. 193), there is no sound basis for the idea that the disk is used in diagnosis.

Consequently, the emphasis in the opinion of the Court upon the addition of the term "diagnosis" to the definition of "drug" in the 1938 Act (Opinion 11-12) does not support the conclusion that the disk is a "drug". Moreover, "diagnosis" is an essential element of "cure" or "mitigation" and articles used in diagnosis were therefore "drugs" under the 1906 Act. Barium sulfate, for example, was regarded as a medicine or drug at least as early as 1926 when it first appeared in the United States Pharmacopeia (Xth Revision).

II. The disk is not used in the treatment of the patient. The trial court, found, instead, that the information obtained from the test, of which the disk is but one part, is used by the physician as a guideline to treatment (Finding of Fact Number 8, App. 194).

Since there is not even a suggestion in the opinion of this Court that Findings Number 7 and 8 are clearly erroneous we are at a loss to understand how the conclusion could be reached that the disk is used either in diagnosis or treatment.

We stated in our brief (p. 38) that—

> "Even if the finding of the District Court that the term 'drug' is limited to substances administered or applied to patients were entirely ignored, we submit that the evidence shows that the disks are nevertheless not 'drugs' because they are not used in 'diagnosis' or 'treatment' . . .".

It is, therefore, not accurate to suggest that the status of the disk is dependent upon "the same two-step analysis relied on by the courts below" (Opinion pp. 8-9). This simplified approach ignores Findings 7 and 8 and the evidence that the disk is not used in "diagnosis" or "treatment". The "two-step analysis" must be put aside, regardless of its validity or invalidity where, as here, it has been shown by expert testimony that the disk is not used in "diagnosis" or "treatment". There is no basis for assuming that Congress used those medical terms of art any differently than they are used in medical science.

III. It is stated in the opinion that "viewing the structure, the legislative history, and the remedial nature of the Act, we think it plain that Congress intended to define 'drug' far more broadly than does the medical profession". (p. 9).

It is respectfully submitted that this statement is not supported by the legislative record cited in the opinion insofar, at least, as it applies to the only clause of the definition of drug (Section 201(g)(1)(B)) with which we are here concerned. The opinion (p. 11) cites the statement of Senator Copeland that—

> "The present law defines drugs as substances or mixtures of substances intended to be used for the cure, mitigation, or prevention of disease [Clause (B)]. This narrow definition permits escape from legal control of all therapeutic or curative devices like electric belts, for example. It also permits the escape of preparations which are intended to alter the struc-

> ture or some function of the body, as for example, preperations intended to reduce excessive weight. . ." (78 Cong. Rec. 8960 (1934)).".

The only avowed extension of the definition of drug, therefore, is to "preparations which are intended to alter the structure or some function of the body", an approach incorporated in Section 201(g)(1)(C) and *not* in Clause (B) of that section, which is the only provision pertinent here.

If, therefore, it be a fact that "Congress intended to define 'drug' far more broadly than does the medical profession," it is by virtue of clauses (C) (and perhaps (B)) of Section 201(g)(1) and not by virtue of Clause (B) with which we are here concerned. Congress' intention in this respect is, therefore, not relevant to the question of whether the disk is a "drug".

It is said in the opinion that—

> "If Congress had intended to limit the statutory definition to the medical one, it could have so stated explicitly, or simply have made reference to the official United States Pharmacopoeia (or the National Formulary), as it did in the first of the three subsections of Section 201(g)(1), and let the definition rest there". (p. 10)

It is again clear from this quotation that we have not been successful in our attempt to explain an important aspect of this matter. If the alternative suggested of referring to the official compendia had been followed, many hundreds of substances which are regarded as drugs by the medical profession would have been excluded from the coverage of the statute.

Neither the Pharmacopoeia nor the Formulary purport to include all drugs recognized as such by the medical profession. Even new drugs cleared as safe and efficacious for use under Section 507 of the Food, Drug, and Cosmetic Act are not admitted to the official compendia until

the Committees on Admissions are satisfied of their therapeutic usefulness. It is apparent, therefore, that in order to extend the statute to all articles recognized as drugs by the medical profession Congress was required to go further than a reference to the official compendia and it did so, both in the 1906 and the 1938 Acts.

IV. It is stated in the opinion that "the parties do not disagree here, that a literal reading of the words 'intended for use in the . . . cure, mitigation, [or] treatment' of disease 'clearly has application' to the Bacto-Unidisk . . ." and that "Thus, the essential question for our determination is whether Congress intended the definition of drug to have the broad coverage the Courts below and the parties agree its words allow" (p. 9).

Respondent did not and does not agree to this proposition. This is made clear in our brief (pp. 33 et seq.). The District Court's findings and conclusion of Law Number 4 are inconsistent with it.* Findings Number 7 and 8 clearly exclude the application of "diagnosis" and "treatment" to the disk and they are not subject to modification by a preceding memorandum opinion.

V. The opinion states that—

> "Thus, it is clear that two parallel definitions [of 'drug' and 'device'] were provided for semantic reasons only . . . . No practical significance to the distinction between the two words arose until the pre-market clearance provisions, similar to the certification regulations for antibiotics enacted in 1945, were added after a drug tragedy in the fall of 1937." (p. 14).

An examination of the provisions of S. 5 (75th Congress), to which the new drug pre-clearance provisions

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* Conclusion of Law Number 4: "The seized article does not purport to be nor is it represented to be a drug within the meaning of 21 U.S.C. 321(g). It is not intended for drug use (see Findings Numbers 9 and 10) and it is the intended use which determines its status under that Section . . ."

were added, and of the Act as enacted in 1938, shows that this statement is far from accurate. The following provisions of S. 5 and the 1938 Act were then and are now applicable to drugs and *not to devices*: ** Sections 501 (a) (3), 501(a) (4), 501(b) and 501(d) relating to adulteration of drugs and Sections 502(e), 502(g), 502 (h), and 502(i), relating to misbranding of drugs.

These are and were important provisions of S. 5 and of the statute as enacted in 1938, which are of practical and serious legal significance to the distinction between the two words "drug" and "device". Others have been enacted since which strongly emphasize this significance.

It was pointed out in our brief (pp. 31-33), that the public health argument of the Government would result in application of the definition of "drug" to any article, including devices, where, in the opinion of the Food and Drug Administration, the more restrictive requirements of the statute relating to drugs, new drugs, and antibiotic drugs would offer greater protection to the public than those provisions relating to devices; that, since this approach offers no standard for determining the limits of the scope of the definition of "drug" the marketer of drugs and devices cannot know in advance how to avoid an unlawful course of action; and that to leave to conjecture the distinction between "drug" and "device" in a liability-without-fault criminal statute such as the Federal Food, Drug and Cosmetic Act would result in an unconstitutionally vague application of the statute within the meaning of *M. Kraus and Bros. Inc.* v. *United States*, 327 U.S. 614, 621-622 (1946).

The argument is pointed up by the many critical provisions of the statute, above listed in part, which are brought into play when the Food and Drug Administration regards an article as a "drug" but which are not operative if the article is a "device". If the marketer

** Dunn, Federal Food, Drug and Cosmetic Act, 970, 980-982.

decides that such a product is a device and the agency decides that it is a drug, the marketer may be subjected to criminal prosecution on at least five counts and, if convicted, to imprisonment for one year or a fine of $1,000 or both such imprisonment and fine (Section 303(a)). This result would follow regardless of any "consciousness of wrongdoing" (*United States* v. *Dotterweich*, 320 U.S. 277, 284 (1943)).

Finally, the examples of some of the products held to be devices by the Food and Drug Administration and the courts are so far removed from the mere mechanical type of device referred to in the opinion of the Court that one attempting to determine in which category the agency would classify a given product would be totally at a loss to decide upon which course of action to pursue. Two of the examples cited in our brief are of products which are notably similar to sensitivity disks, since they involve the use of the patient's urine or blood (Respondent's Brief pp. 48-40). There are many products heretofore regarded by the Courts and the Food and Drug Administration as "devices" which do not fall within the rigid classification made in the Court's opinion.

VI. It is fully evident as is shown by the history of the certification regulations applicable to sensitivity disks, by the proceedings in the District Court, and by the brief and argument of the Government in the Court of Appeals and in this Court, that the principal reliance of the Government in this case has been upon the allegation of danger to public health from the results of a sensitivity test in which a faulty disk was used. The Government failed to support this allegation either at the trial or in this Court, but the Court has accepted it as a determining factor in this case.

The opinion states that—

> "It is enough for us that the expert agency charged with the enforcement of remedial legislation has determined that such regulation is desirable for the

public health, for we are hardly qualified to second-guess the Secretary's medical judgment" (p. 8).

It is submitted that the only reason for relying upon the agency's judgment concerning the public health matter would be to show the existence of a remedial purpose which would justify the extension of the definition of "drug" beyond the meaning of Clause (B) of the definition (Section 201(g)(1)) as established by the evidence at the trial and the findings of fact of the lower Court. In fact, there is no other apparent reason for even referring to that judgment of the Secretary.

This seems evident from those portions of the Court's opinion invoking the purpose of the Act of protecting the public health (p. 15, preceding "IV") and the expressions of apprehension that an exclusion of discs from the definition of "drug" "might undercut the value of testing the antibiotics themselves, for such testing would be a useless exercise if the wrong drug were ultimately administered, even partially as the result of an unreliable disk" (p. 16). The opinion thus evokes the public health claim of the Government as a prime basis for reversal of the decisions of the lower courts.

This approach by the Court has been traditional in cases where it was apparent that the element of protection of the public health was involved, as in *Sullivan* * and *Dotterweich* ** cited on page 15 of this Court's opinion. In both of those cases there was no issue as to whether the articles involved were drugs. Consequently, the question of the relation of the public health to the regulation of such drugs was not in issue (as it now is here).

The regulations in connection with which the judgment of the agency was made were not subject to the public hearing procedures of the Act, as are some regulations

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* *United States* v. *Sullivan*, 332 U.S. 689 (1948).

** *United States* v. *Dotterweich*, 320 U.S. 277 (1943).

thereunder, nor is the judgment upon which they are based conclusive upon the Courts. This was recognized and noted by the Court of Appeals (App. 202).

With all of these factors in mind we must conclude that the Court's view that the judgment of the Secretary on this prime issue should not be disturbed or "second-guessed", deprives respondent of any real hearing in this matter, for, despite its constant emphasis upon this issue, and the prominence which it has received, the government is protected from all questioning of the validity of the Secretary's (Commissioner's) judgment by this Court's ruling.

Once the regulations extending the definition of "drug" to sensitivity disks were issued and were challenged in the seizure proceeding in the District Court, the only forum available either to the Government or claimant-respondent to support or challenge the basis for the regulations—their alleged desirability for protection of the public health—was by evidence at the trial on the question of whether, because of the public health issue, the remedial purpose of the statute could be invoked to justify a construction of Clause (B) of Section 201(g)(1) which goes beyond its meaning in medical science.

The refusal to consider such evidence and the acceptance of the agency's judgment without critical examination of it on the basis of the facts precludes respondent from the opportunity of defending itself to which it is entitled. We earnestly appeal to the Court to reconsider this decision in the light of the evidence of record, the literature cited by the Government itself in this Court, and the salient fact that throughout the pertinent time-periods the Government has been unable to produce a single instance of harm to a patient or even of a test report misleading to a physician, which was caused by a faulty disk. This, despite the fact that sensitivity disks have been marketed commercially for some 18 or 19 years of which about 12 or 13 were before the certification regulations were issued.

VII. It is shown in respondent's brief (pp. 44-47) that, even if the Bacto-Unidisk is a drug it is not subject to certification because it is fully clear from the legislative history that only antibiotic drugs intended for administration or application to patients were ever intended by the Congress to be certified. As the brief shows, the Department of Health, Education and Welfare itself has recognized that the purpose of the certification provisions of the Act (Section 507) is to subject antibiotic drugs *to be administered to human beings* to batch certification. This purpose obviously does not include sensitivity disks.

It is submitted that this limitation of Section 507 should, itself, require affirmance of the decision of the Court of Appeals. The opinion does not indicate whether the point was considered by this Court.

VIII. There are thousands of laboratory reagents such as the Bacto-Unidisk which are used to make tests indirectly related to the practice of medicine in the sense that the information obtained from such tests is used in one way or another to aid the physician. No person and no organization knows how many of these thousands of products fall within the category of "drugs" under the decision of the Court in this case.

As stated in respondent's brief—

> "There are more than 150 pages in the United States Pharmacopeia (and others in the National Formulary) describing hundreds of laboratory reagents or testing materials for use in making the various tests and assays described in the Pharmacopeia" (p. 37).

The reagents so listed, which are only a few of those now in use, are not regarded as drugs by the Committees on Revision of the official compendia and therefore do not appear in the monograph sections of the compendia. Thus, they are not "recognized" in the sense of Section 201(g)(1)(A) (App. 153-154; 155-157; 160-167).

It is to be anticipated that, under the decision of this Court, a large proportion—perhaps most of those classified as drugs—would be regarded as new drugs and therefore subject to the pre-clearance procedures requiring a showing of safety and effectiveness under Section 505 of the Act. This is because many of these products are either entirely new or are improvements upon predecessor products. The volume of business in these reagents is, in many if not most instances, of such a low order that the ability of manufacturers to continue their production would be questionable in the face of the high expense and the long periods of time required for industry to obtain the necessary evidence to support, and for the Food and Drug Administration to process, a new drug application.

We want to emphasize this point: these thousands of products (some companies manufacture and market as many as 7,000 or more) are not distributed through drug channels and are handled, not by medical supply houses, but by general laboratory supply companies.

It is fully apparent to the affected industry that, if laboratory reagents are to be controlled by a regulatory agency, they must be classified as devices (where, as here, they lend themselves to such a classification) or an entirely new system of regulation must be devised by the Congress. These products simply do not lend themselves to control as "drugs". For example, the Prescription Drug Amendment (Section 503 of the Act) obviously is inapplicable because laboratory reagents never come into the hands of patients; and, if an article such as the Bacto-Unidisk is indeed a drug, it could be labeled "for use in the treatment of bacterial infections"—obviously a false claim. If they are not classified as "devices" and no new regulatory system is provided, confusion and uncertainty and the loss by laboratories of testing tools which are of benefit to the physician in his practice, will inevitably result.

These problems have patently not been given serious consideration by the Food and Drug Administration. The inability of the marketer of laboratory reagents to tell whether his products are "drugs" has been markedly increased by the decision of this Court and the regulatory agency is now free to pick and choose which reagents it will regulate as drugs and which it will ignore.

It is submitted that, where so many thousands of "little" products are concerned the situation with which those who market them are faced is unhealthy and unwarranted.

CONCLUSION

It is respectfully submitted that rehearing of this matter should be granted and that the decision of the Court of Appeals should be affirmed.

Respectfully submitted,

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CERTIFICATE OF COUNSEL

I hereby certify that the foregoing petition for rehearing is presented in good faith and not for delay.

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May, 1969